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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,709	08/22/2001	Charles A. Morris	1533.0520001	6249

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/933,709	Applicant(s) MORRIS ET AL.	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-44 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18-44 and 47-52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

In view of the decision by the pre-appeal conference members, the prosecution is reopened.

Upon consideration, the 112, first paragraph rejection is withdrawn.

In view of the amendment to the claims 19, 27 and 51, the 112, second paragraph rejection is also withdrawn.

Claims included in the prosecution are 18-44 and 47-52.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 18-44 and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al (4,486,435) in combination with Schmidt (4,603, 143) and Rawlins (4,719,228) or Rawlins in view of Schmidt (4,486,435) or Schmidt (4,719,228) by themselves or in combination.

Schmidt et al. teach a free-flowing, non-agglomerated, non-caking vitamin powder composition comprising about 45 to about 60 percent vitamin, about 2 to about 18 percent of corn starch, about 0.2 to about 2 percent hydrophobic silica, and other

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ingredients (col. 8, lines 15-22; col. 5, example 1). Schmidt et al. further teach that the water insoluble carrier can be corn starch (col. 8, line 32). Schmidt et al. also teach that the vitamin can be selected from vitamin H, D, E, K and mixtures thereof as well as vitamin B1, B6, B2, B12, C and mixtures thereof (col. 2, lines 20-34). Lastly, Schmidt et al. teach that the vitamin composition of their invention is suitable for the preparation of tablets (col. 1, line 49). The reference does not specifically discuss stability. However, it is the position of the examiner that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for its intended purpose. What are lacking in Schmidt are the claimed particle sizes of silica.

As discussed before, Schmidt 143 while disclosing free flowing, high density, fat-soluble vitamin powder preparations teaches the use of silica of bigger particle sizes (100 microns). The vitamins include tocopherols, vitamins A, D and K (abstract, col. 2, line 49 through col. 3, line 26, Table 1, Examples and claims).

Rawlins teaches free flowing powders of pharmaceutical agents. According to Rawlins, the silica particles can have a diameters of at lest 10 microns and preferably between 10 microns to 1 mm (abstract, col. 1, lines 48-50; col. 2, lines 24-32; lines 43-47; Example 2 and claims). Example 2 in particular shows the use of silica of diameter 50 microns (Sipernat 50)

It would have been obvious to use the silica of bigger particle sizes 40-50 microns in the compositions of Schmidt et al 435 or 143 with a reasonable expectation of success, since as evidenced by Rawlins, one can obtain free-flowing powders using silica which has a diameter between 10 microns to 1 millimeter, in particular 50 microns.

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Although the references are silent with respect to the density and the surface area of the silica particles, since these are commercially available particles and in the absence of showing otherwise and the criticality of these factors, it is the position of the examiner that Rawlins's silica particles which were obtained commercially possess these properties or manipulatable parameters to obtain the best possible results.

Alternately, the use of vitamins D, E or K as the active agents in the compositions of Rawlins who teaches free flowing powders of active agents with silica particles of 50 microns with the expectation of obtaining similar results since the references of Schmidt (435) and (143) each teach that they are free flowing powders of these vitamins can be prepared using silica particles.

4. Claims 18-44 and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt et al (4,486,435) in combination with Schmidt (4,603, 143) and Rawlins (4,719,228) or Rawlins in view of Schmidt (4,486,435) or Schmidt (4,719,228) by themselves or in combination as set forth above, further in view of Drake (4,010,073).

The teachings of Schmidt (435), (143) and Rawlins have been discussed above. What is lacking in these references is the teaching that the starch used is a redried starch.

Drake while disclosing free-flowing powders of an enzyme composition teaches that commercial starch generally contains between 10 to 14 % moisture and the resultant product has poor storage stability. Drake further teaches that redried starch with a moisture content of 3 % is commercially available and that it increases the

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storage stability. The compositions of Drake further include silica (abstract, col. 2, lines 29-51, examples and claims).

The use of redried starch instead of starch in the teachings of Schmidt (435), (143) and Rawlins would have been obvious to one of ordinary skill in the art since Drake teaches high moisture content of regular starch which leads to poor storage stability and hence the use of redried starch.

Applicant's arguments have been considered, but are deemed to be moot in view of the new rejections.


The examiner cites the reference, 'silicas and silicates' which gives the particle sizes of Sipernats (silicas).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK